Initial Approval Date: July 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Crohn's Disease Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Infliximab (Remicade®, Inflectra®, Ixifi™, Renflexis®)
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™)
Certolizumab (Cimzia®)
Vedolizumab (Entyvio®)
Natalizumab (Tysabri®)
Ustekinumab (Stelara®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a gastroenterologist.
- Patient must have had an adequate trial (at least 90 consecutive days within the past 120 days) of or contraindication to methotrexate for the maintenance of remission. Remission can be induced by corticosteroids (not listed).[1] If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.[1]
- For all agents listed, the preferred PDL drug, which treats this PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of one of the following:
    - Patient has moderately to severely active disease, defined as at least one of the following:
        - Crohn's Disease Activity Index (CDAI) score > 220.[1]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits for Crohn's Disease (CD) Agents.[2-7]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-12 and -23 Inhibitors			
Ustekinumab (Stelara™)	Moderate to Severe active CD	≥ 18 years	IV: ≤ 55 kg: 260 mg as a single dose. >55-85 kg: 390 mg as a single dose. >85 kg: 520 mg as a single dose. SC: 90 mg every 8 weeks beginning 8 weeks after the IV induction dose.
Selective Adhesion-Molecule Inhibitor			
Natalizumab (Tysabri®)	Moderate to Severe active CD	≥ 18 years	300 mg IV every 4 weeks
Vedolizumab (Entyvio®)	Moderate to Severe active CD	≥ 18 years	300 mg IV at 0, 2, and 6 weeks, and then every 8 weeks thereafter.
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®)	Moderate to Severe active CD	≥ 6 years and at least 17 kg	17- <40 kg: 80 mg initially SC on day 1, followed by 40 mg 2 weeks later (day 15) and then 20 mg every other week beginning 2 weeks later (day 29). ≥ 40 kg: 160 mg initially SC on day 1 (given on day 1 or split and given over 2 consecutive days), followed by 80 mg 2 weeks later (day 15) and then 40 mg every other week beginning 2 weeks later (day 29).
Adalimumab (Amjevita™, Cyltezo™, Hyrimoz™)	Moderate to Severe active CD	≥ 18 years	≥ 40 kg: 160 mg initially SC on day 1 (given on day 1 or split and given over 2 consecutive days), followed by 80 mg 2 weeks later (day 15) and then 40 mg every other week beginning 2 weeks later (day 29).
Certolizumab (Cimzia®)	Moderate to Severe active CD	≥ 18 years	400 mg initially SC at weeks 0, 2, and 4 followed by 400 mg every 4 weeks.
Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™)	Moderate to Severe active CD	≥ 6 years	5 mg/kg at IV 0, 2, and 6 weeks, then every 8 weeks. May increase to 10mg/kg if response is lost.

SC: subcutaneous. IV: intravenous

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Prescriber must provide at least of the following response measure(s):
  - Clinical response, defined as Crohn's Disease Activity Index (CDAI) reduction of at least 100 compared to baseline.[4,5,7]
  - Induction of remission, defined as CDAI < 150.[1]
  - Complete or partial mucosal healing as determined by endoscopy.[1]
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of CD

Conventional Crohn's Disease Therapies	
Generic Name	**Brand Name**
Azathioprine	Azasan®, Imuran®
Mercaptopurine	Purinethol®
Methotrexate	Trexall®, Rheumatrex®, Otrexup®, Rasuvo®

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan® (rituximab)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Simponi® (golimumab)
Cimzia® (certolizumab)	Ilumya™ (tildrakizumab-asmn)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Inflectra® (infliximab-dyyb)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Ixifi™ (infliximab-qbtx)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kevzara® (sarilumab)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Kineret® (anakinra)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Nucala® (mepolizumab)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Olumiant® (baricitinib)	Xeljanz® (tofacitinib)
Erelzi™ (etanercept-szzs)	Orencia® (abatacept)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xolair® (omalizumab)
Fasenra™ (benralizumab)	Renflexis® (infliximab-abda)	

References

1. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018; 113:481-517. https://gi.org/guidelines/. Accessed 5/22/19.
2. Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech, Inc; Jun 2018.
3. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; Dec 2018.
4. Cimzia (certolizumab) [package insert]. Smyrna, GA: UCB, Inc.; Mar 2019.
5. Entyvio (vedolizumab) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2019.
6. Tysabri (Natalizumab) [package insert]. Cambridge, MA: Biogen Inc.; Apr 2018.
7. Stelara (Ustekinumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; Jun 2018.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER

DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE DATE